pany. **RESULTS:** Publicly-available guidance on RWE data collection by HTA and reimbursement authorities is almost entirely lacking, with the exception of The Netherlands, where there is a well-established process for post-launch data collection. Published data sources were limited to two studies, both with a focus on safety. Market access specialists highlighted five categories of RWE data types. All countries expressed a requirement for patient characteristics, treatment patterns and effectiveness. Resource use and quality of life were considered supportive but not essential. A current or planned melanoma registry was identified in most countries, but the range of data collected and national coverage varied substantially. **CONCLUSIONS:** There is very little formal guidance on RWE requirements in Europe, and no consistency across countries. In some cases (France, Germany, The Netherlands), there is an established infrastructure, although there is substantial variation between countries. Market access specialists anticipate increasing requirements for RWE in coming years but, currently, such data can be considered supportive rather than essential. Therefore, manufacturers with new or development drugs must anticipate future, expanding requirements for RWE in their post-launch data generation programmes.

PCN37

NEW DRUGS IN NON-SMALL CELL LUNG CANCER: DISPARITIES IN REQUIREMENTS FOR POST-LAUNCH REAL-WORD EVIDENCE IN EUROPE

Floyd D, Langham J

PHMR Ltd, London, UK

OBJECTIVES: To determine country-specific requirements for real-world evidence (RWE) in Europe to support ongoing market access for new drugs to treat non-small cell lung cancer (NSCLC). Several new classes of drugs for NSCLC are coming to market and there is likely to be much competition. RWE is expected to play an important part in differentiating the new products and their most suitable target patient populations. **METHODS:** We reviewed published health technology assessments (HTAs) and reimbursement agency web sites to determine data sources for, or guidance on, RWE in France, Germany, Italy, The Netherlands, Spain, Sweden and the UK. In addition, we performed a pragmatic review of peer-reviewed literature to identify types of NSCLC RWE being published, and collected the views of market access specialists on RWE requirements among country representatives of a global pharmaceutical company. **RESULTS:** Publicly-available guidance on NSCLC RWE data collection by HTA and reimbursement authorities is currently lacking. Likewise, data sources are highly limited in number and scope and there were no publications featuring feasible registries. Market access specialists highlighted five categories of RWE data types. All countries expressed a requirement for patient characteristics, treatment patterns and effectiveness. Resource use and quality of life were considered supportive but not essential. No current registries are able to meet these requirements. **CONCLUSIONS:** Formal guidance on RWE requirements in NSCLC in Europe is lacking and there is a need for registries to capture the range of data types highlighted by market access specialists to obtain and maintain market access. Given the level of development in the NSCLC field, and the number of likely new market entrants, manufacturers with new or developmental drugs need to help establish an infrastructure for collecting NSCLC RWE in Europe.

PCN38

SYMPTOMS, CONCOMITANT CONDITIONS AND CARDIAC RISK IN EUROPEAN HYDROXYUREA TREATED POLYCYTHEMIA VERA PATIENTS

Graham A[1], Milligan G[2], Manuel L[1], Taylor-Stokes G[1]

[1]*Adelphi Real World, Manchester, UK,* [2]*Adelphi Real World, Bollington, UK*

OBJECTIVES: Polycythemia Vera (PV) is associated with an overproduction of blood cells which leads to increased risk of blood clots and associated cardiovascular (CV) complications and may result in increased morbidity and mortality. This analysis seeks to evaluate the impact of Hydroxyurea (HU) treatment on symptoms, concomitant conditions and cardiac risk. **METHODS:** Data was drawn from the Adelphi PV Disease Specific Programme, a cross sectional survey of physicians in 8 European countries. 171 specialists completed patient record forms (PRFs) on 969 individuals diagnosed with PV including details of concomitant conditions, symptoms, treatment history, cardiac and/or thrombosis risk status and control status (both defined by the physician). Each physician completed a PRF for the last 6 consulting patients. **RESULTS:** 499 patients currently receiving HU treatment, for at least 3 months post diagnosis, were included in the analysis. At diagnosis 348 (70%) patients presented as symptomatic, 174 (35%) experienced headaches, 168 (34%) fatigue/weakness/tiredness and 166 (33%) pruritus/itching. 328 (66%) had concomitant conditions, principally hypertension 204 (41%) and hyperlipidaemia 106 (21%). 277 (56%) patients presented with splenomegaly with 99 (20%) reporting this as moderate/massive. Cardiac events and/or thrombosis risk was reported as high in 283 (57%) patients. Despite current use of HU, 216 (43%) patients are reported as being symptomatic, 110 (22%) due to fatigue/weakness/tiredness, 44 (9%) pruritus/itching and 34 (7%) headache. 306 (61%) experience concomitant conditions with hypertension remaining a problem for 186 (37%) patients. 51 (10%) patients report moderate/massive splenomegaly whilst CV risk remains high for 156 (31%) of patients. 86 (17%) patients are not currently considered to be controlled. **CONCLUSIONS:** These findings indicate that HU fails to adequately reduce cardiac risk in a proportion of PV patients. Despite treatment almost 1/5 (17%) patients were not considered to be controlled and 2/5 (43%) reported symptoms; hence need exists for better treatments.

PCN39

ASSESSING THE LEVEL OF RESISTANCE/INTOLERANCE TO HYDROXYUREA THERAPY AMONGST PATIENTS WITH POLYCYTHEMIA VERA IN EUROPE

Manuel L[1], Milligan G[2], Graham A[1], Taylor-Stokes G[1]

[1]*Adelphi Real World, Manchester, UK,* [2]*Adelphi Real World, Bollington, UK*

OBJECTIVES: Assess the level of resistance/intolerance to Hydroxyurea (HU) therapy in Polycythemia Vera (PV) patients in the real world setting across Europe, based on the European Leukemia Net (ELN) consensus paper. **METHODS:** Data was drawn from the Adelphi PV Disease Specific Programme, a cross-sectional survey of physicians in 8 European countries. 171 specialists completed patient record forms (PRFs) on 969 individuals diagnosed with PV including details of diagnosis, concomitant conditions, symptoms, laboratory values and treatment history. Data for patients currently receiving HU therapy for more than 3 months were compared with 4 elements of the ELN consensus paper (need for phlebotomy, uncontrolled myeloproliferation, failure to reduce massive splenomegaly and presence of leg ulcers). **RESULTS:** 499 of the 969 patients (51%) were currently receiving HU for a period of more than 3 months. They had a mean age of 68.5 years and had been diagnosed for an average of 39.1 months; 58% were male. Based on the ELN consensus criteria published by the British Journal of Haematology (Barosi et al, 2009), 200 (40%) of those currently receiving HU are classified as resistant/intolerant to HU-therapy. 139 patients (70%) were receiving phlebotomy on average 3.4 times in the past 6 months, 61 (31%) had uncontrolled myeloproliferation (platelet count greater than 400x 109/L and white blood cell count greater than 10x 109/L), 5 (3%) had ulcers and 1 (1%) had massive splenomegaly. 102 (51%) physicians reported that they are not completely satisfied with HU treatment, with inadequate response the main cause of dissatisfaction. **CONCLUSIONS:** This analysis indicates that a proportion of patients continue to receive HU therapy despite being classified as resistant/intolerant according to the ELN consensus paper and a lack of satisfaction amongst physicians. The data support the need for more drug options in later lines of therapy, for patients resistant/intolerant to HU therapy.

PCN40

THE IMPACT OF FIRST-LINE TYROSINE KINASE INHIBITORS (TKIS) ON OVERALL SURVIVAL IN PATIENTS WITH ADVANCED NON-SMALL CELL LUNG CANCER (NSCLC) AND ACTIVATING EPIDERMAL GROWTH FACTOR RECEPTOR (EGFR) MUTATIONS: META-ANALYSIS OF MAJOR RANDOMIZED TRIALS BY MUTATION TYPE

Kato T[1], De Marinis F[2], Spicer J[3], Sebastian M[4], Griebsch I[5], Märten A[5], Lungershausen J[5], Shah R[6]

[1]*Kanagawa Cardiovascular and Respiratory Center, Yokohama, Japan,* [2]*European Institute of Oncology, Milan, Italy,* [3]*King's College London, London, UK,* [4]*Johann Wolfgang Goethe University Medical Center, Frankfurt am Main, Germany,* [5]*Boehringer Ingelheim GmbH, Ingelheim, Germany,* [6]*Maidstone and Tunbridge Wells NHS Trust, Kent, UK*

OBJECTIVES: EGFR mutation-positive NSCLC represents a distinct subtype of NSCLC and its first-line treatment generally comprises erlotinib, gefitinib or afatinib. These agents have all shown progression-free survival improvement vs platinum-doublet chemotherapy (CT). However, a recent pair-wise meta-analysis of phase III clinical trials based on individual patient-level data (n=1231) demonstrated that the reversible EGFR TKIs, erlotinib and gefitinib, do not prolong overall survival (OS) vs CT, neither for the overall patient population nor for the individual mutation subtypes, exon 19 deletions (Del19) and L858R.1 Here, we present a broader pair-wise meta-analysis including studies of the irreversible ErbB family blocker afatinib vs CT, as well as studies of erlotinib and gefitinib. **METHODS:** Patients with common EGFR mutations (Del19 or L858R) treated with either afatinib (LUX-Lung 3, LUX-Lung 6), erlotinib (ENSURE, EURTAC, OPTIMAL) or gefitinib (IPASS, NEJ002, WJTOG3405) in phase III clinical trials vs CT were included. Pooled treatment estimates using the inverse variance weighted method were calculated for all TKI vs CT comparisons in patients with Del19 or L858R. **RESULTS:** In total, data from 1037 patients with Del19 and 816 patients with L858R mutations were analyzed. Afatinib significantly improved OS vs CT in patients with Del19 (HR [95% CI]: 0.59 [0.45–0.77]). For patients with Del19 there was no significant difference in OS, compared with CT, for either erlotinib (HR [95% CI]: 1.03 [0.77–1.38]) or gefitinib (HR [95% CI]: 0.90 [0.70–1.17]). None of the agents improved OS vs CT in patients with L858R mutations (afatinib: HR [95% CI] 1.25 [0.91–1.71]; erlotinib: 0.98 [0.72–1.35]; gefitinib: 1.11 [0.81–1.54]). **CONCLUSIONS:** No differences in OS were observed in the overall EGFR mutation-positive or the L858R population for afatinib, erlotinib, or gefitinib. In contrast to other TKIs, afatinib showed a significant OS benefit vs CT in Del19 patients. 1Lee C, et al. J Clin Oncol 2015;33(suppl):abstract 8072

PCN41

COMPARATIVE EFFICACY OF TREATMENTS FOR PREVIOUSLY TREATED ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC): A NETWORK META-ANALYSIS

Zhang J[1], Zhou Z[2], Cai X[2], Signorovitch J[3]

[1]*Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA,* [2]*Analysis Group, New York, NY, USA,* [3]*Analysis Group, Boston, MA, USA*

OBJECTIVES: To compare the efficacy of available treatments in patients with previously treated advanced/metastatic non-small cell lung cancer (NSCLC) **METHODS:** Clinical trials of ceritinib, crizotinib, pemetrexed, docetaxel, erlotinib, and best supportive care (BSC) in previously treated, crizotinib-naïve NSCLC were identified in a systematic literature review (up to March 2014). Since only single-arm trials were available for ceritinib, a matching-adjusted indirect comparison between ceritinib trials and similarly-designed crizotinib trials was used to link ceritinib into the evidence network. A Bayesian-based network meta-analysis (NMA) was then conducted to compare overall survival (OS), progression-free survival (PFS) and overall response rate (ORR) among the studied treatments. Relative treatment effects and corresponding 95% credible intervals (CrIs) were estimated as well as the posterior efficacy rankings. **RESULTS:** Fourteen clinical trials, including two ceritinib single-arm trials (ASCEND-1 [NCT01283516], ASCEND-3 [NCT01685138]), were included. Sample sizes ranged from 49 to 488 patients per arm. Ceritinib was associated with significantly prolonged OS compared to crizotinib (hazard ratio [HR]: 0.58; 95%CrI: 0.41-0.83), pemetrexed (0.44; 0.26-0.76), docetaxel (0.47; 0.28-0.82), erlotinib (0.44; 0.26-0.80), and BSC (0.29; 0.16-0.55). Ceritinib also showed improved PFS compared to crizotinib (0.45; 0.18-1.56), pemetrexed (0.18; 0.06-0.83), docetaxel (0.17; 0.06-0.84), erlotinib (0.15; 0.05-0.90), and BSC (0.08; 0.02-0.69). Ceritinib increased the odds of achieving ORR by 38% compared to crizotinib, and was associated with ≥3 times higher ORR compared to other treatments. Ceritinib was the most efficacious treatment in terms of OS (posterior probability 99%), PFS (92%) and ORR (63%) among all treatments, followed